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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/502,414

01/11/2005

Berit Johansen

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02/18/2009

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EXAMINER

DICKINSON, PAUL W

ART UNIT

PAPER NUMBER

1618

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DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/502,414	Applicant(s) JOHANSEN ET AL.	
	Examiner PAUL DICKINSON	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11/17/2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-14 and 17 is/are pending in the application.
- 4a) Of the above claim(s) 5, 11 and 12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-4, 6-10, 13, 14 and 17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's arguments, filed 11/17/2008, have been fully considered but they are not deemed to be fully persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objects are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Response to Arguments

Claim Rejections - 35 USC § 103

The rejection of claims 2-4, 6-10, 13, 14 and 17 under 35 U.S.C. 103(a) as being unpatentable over Johansen et al (Prog Surg. Basel, Karger, 1997) in view of Holmeide et al (J. Chem. Soc., Perkin Trans., 2000) is maintained.

The Declaration under 37 CFR 1.132 filed 11/17/2008 is insufficient to overcome the above rejections of claims 2-4, 6-10, 13, 14 and 17 set forth in the last Office action. Applicant argues that compounds of formula (I) selectively inhibit type IVa PLA₂ enzymes. Applicants were the first to recognize that compounds of formula (I) potently reduced eicosanoid production via the selective inhibition of IVa PLA₂ enzymes. The cytosolic group IV PLA₂ enzyme described by Johansen et al is not the same as the IVa PLA₂ enzyme described by Applicant. Applicant's IVa PLA₂ enzyme is in fact a subtype of the enzyme described by Johansen et al. Applicant argues that because Johansen et al failed to recognize the importance of IVa PLA₂ in psoriasis pathology, this constitutes a teaching away from administering a compound of formula (I) to treat

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psoriasis. Johansen et al does not teach a correlation between levels of cPLA₂ and psoriasis, but merely states that selective inhibitors for PLA₂ enzymes should have a potential in curing some of the inflammatory symptoms, including epidermal hyperproliferation due to increased leukotriene production, related to eicosanoid production and cell activation in both epidermis and dermis in psoriasis. Johansen et al does not provide any evidence to back up this conclusory statement that fails to represent the complexity of disease pathology and in particular the complexity of the PLA₂ family of enzymes. Applicant argues that Holmeide et al describes the synthesis of potential inhibitors of generic type IV PLA₂, but there is no showing that Compound 18 is a selective inhibitor of cPLA₂, much less a showing that the compound selectively inhibits type IVa PLA₂ enzymes. Further, Holmeide et al fails to teach or suggest the use of such compounds for the treatment of psoriasis.

Applicant's arguments have been fully considered but are not found persuasive. The scope of the instant claims is a method of treating psoriasis comprising administering to a mammal an effective amount of the recited compounds, thereby selectively inhibiting the enzyme IVa PLA₂.

The Examiner maintains that the teachings of Johansen et al suggest it would be reasonable to attempt treatment of psoriasis by administering PLA₂ inhibitors. The reference teaches that "selective inhibitors for PLA₂ enzymes should have a potential in curing some of the inflammatory symptoms, including epidermal hyperproliferation due to increased leukotriene production, related to eicosanoid production and cell activation in both epidermis and dermis in psoriasis" (see page 230, last paragraph). Applicant

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argues that Johansen et al "merely describes a correlation between levels of type II PLA₂, termed npPLA₂... and psoriasis." The Examiner maintains that the teaching quoted above suggests that it would have been reasonable to at least try selective inhibitors for PLA₂ enzymes to treat psoriasis with an expectation of success. That no data is presented to back this statement up does not detract from, or teach away from, the clear teaching above.

Regarding Holmeide et al, the Examiner agrees that there is no enzyme inhibition study provided by the reference. This notwithstanding, Holmeide et al suggests that Compound 18 would inhibit cPLA₂ with a reasonable expectation of success. Specifically, Holmeide et al states "We were particularly interested in the trifluoroketone 1, derived from arachidonic acid, which is a **potent** inhibitor of cPLA₂." (emphasis mine) (page 2271, col 1, second paragraph). Holmeide et al proceeds to prepare chemically related compounds, such as Compound 18, and, based on their structural similarity to the potent inhibitor trifluoroketone 1, teaches that these compounds may serve as inhibitors of cPLA₂. That Holmeide et al does not appreciate the utility of the compound to selectively inhibit IVa PLA₂ is immaterial to the basis of the rejection. Johansen et al teaches that selective inhibitors for PLA₂ enzymes have potential in treating psoriasis, and it would be obvious to try selective PLA₂ enzymes inhibitors, such as those disclosed by Holmeide et al, to treat psoriasis. A composition cannot be separated from its properties, and the administration of the compound would inherently selectively inhibit the enzyme IVa PLA₂. "[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning,

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does not render the old composition patentably new to the discoverer.” *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).” MPEP § 2112. Thus, there is no showing of an unexpected result, but a showing of a property and this property flows from the combination as set forth in the prior art rejection, which arrives at the instantly claimed method.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PAUL DICKINSON whose telephone number is (571)270-3499. The examiner can normally be reached on Mon-Thurs 9:00am-6:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

Paul Dickinson
Examiner
AU 1618

February 4, 2009